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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number: 01194-513001
I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Mail Stop AF, Commissioner for Patents, Box 1450, Alexandria, VA 22313-1450. March 2, 2007 Date of Deposit Signature James Coughlan Typed or Printed Name of Person Signing Certificate	Application Number 10/690,436	Filed October 22, 2003
	First Named Inventor Sharon Mi Lyn Tan	
	Art Unit 3763	Examiner LoAn H. Thanh

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a Notice of Appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☒ attorney or agent of record 40,978
(Reg. No.)
- ☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34

Signature

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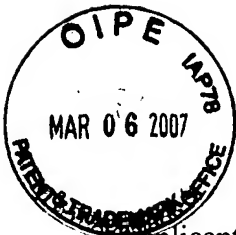
Telephone number

March 2, 2007

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below'.

☒ Total of 1 forms are submitted.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Sharon Mi Lyn Tan
Serial No. : 10/690,436
Filed : October 22, 2003
Title : CATHETER WITH A SIDEARM FOR DELIVERY OF ANTIMICROBIAL AGENTS TO PREVENT INFECTION

Art Unit : 3763
Examiner : LoAn H. Thanh
Conf. No. : 3696

Mail Stop AF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REVIEW REQUEST

Pursuant to United States Patent and Trademark Office OG Notices: 12 July 2005 - New Pre-Appeal Brief Conference Pilot Program, a request for a review of identified matters on appeal is hereby submitted with the Notice of Appeal. Review of these identified matters by a panel of examiners is requested because the rejections of record are clearly not proper and are without basis, in view of a clear legal or factual deficiency in the rejections. All rights to address additional matters on appeal in any subsequent appeal brief are hereby reserved.

Remarks

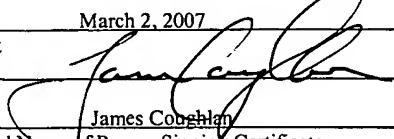
Claims

Claims 1-26 are presented for pre-Appeal Brief review. Claims 1, 10 and 19 are the only independent claims. These claims read as follows (Amendment mailed May 9, 2006, pp. 4-8):

1. An infection management system, comprising:
a catheter with a lumen extending therethrough;
a side-arm tube extending laterally from a side of the catheter, wherein the side-arm tube is located in a region of the catheter which remains outside a patient's body, and
a lumen through the side-arm tube communicates with the catheter lumen;
a one-way valve which prevents fluid flow from the catheter lumen through the side-arm tube lumen without preventing fluid flow through the

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James Coughlan
Typed or Printed Name of Person Signing Certificate

catheter lumen; an antimicrobial agent-bearing intervention device configured to be inserted through the side-arm tube lumen and the one-way valve into the catheter lumen; and

a cap coupled to the antimicrobial agent-bearing intervention device, the cap being configured so that a user can handle the antimicrobial agent-bearing intervention device without directly contacting the antimicrobial agent-bearing intervention device.

10. An infection management method, comprising:

providing a catheter with a lumen extending therethrough, a side-arm tube extending laterally from a side of the catheter, wherein the side-arm tube is located in a region of the catheter which remains outside a patient's body and a lumen through the side-arm tube communicates with the catheter lumen, and a one-way valve located to prevent fluid flow from the catheter lumen through the side-arm tube lumen without preventing fluid flow through the catheter lumen; and

inserting an antimicrobial agent-bearing intervention device a cap through the side-arm tube and the one-way valve into the catheter lumen,

wherein the cap is coupled to the antimicrobial agent-bearing intervention device, and the cap is configured so that a user can handle the antimicrobial agent-bearing intervention device without directly contacting the antimicrobial agent-bearing intervention device.

19. An anti-infection catheter, comprising:

a main catheter tube with a lumen extending therethrough;

a side-arm tube extending laterally from a side of the main catheter tube,

wherein

the side-arm tube is located in a region of the catheter which remains outside a patient's body, and

a lumen through the side-arm tube communicates with the lumen of the main catheter tube;

a one-way valve adapted to permit passage of an antimicrobial agent-bearing intervention device between the side-arm tube lumen and the main catheter tube lumen while preventing fluid flow from the main catheter tube lumen through the side-arm tube lumen, wherein the one-way valve does not prevent fluid flow through the main catheter tube lumen; and

a cap coupled to the antimicrobial agent-bearing intervention device,

wherein the cap is configured so that a user can handle the antimicrobial agent-bearing intervention device without directly contacting the antimicrobial agent-bearing intervention device.

Appellants submit that the Examiner clearly erred in that the cited references do not, alone or in combination, disclose the subject matter claimed by Appellants.

Rejection under 35 U.S.C. § 103(a)

The Examiner rejected claims 1-26 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,371,944 ("Liu") in view of U.S. Patent No. 5,588,443 ("Davidson"), and further in view of U.S. Patent No. 5,413,561 ("Fischell"). In particular, the Examiner stated "Liu [] disclose[s] a system for use in the body comprising a catheter 7 [having] a side arm [and] a lumen through the side arm 9" (Office Action mailed January 9, 2007, p. 2.) But, rather than being a catheter, Liu's element 7 is a needle. (See, e.g., Liu col. 2, lines 47-50.) As one skilled in the art would understand, a needle of the type disclosed by Liu is not a catheter. Indeed, when characterizing the manner in which a catheter is commonly disposed within a blood vessel (Id. col. 1, lines 26-29):

A guide wire is passed through a needle which has been inserted into the blood vessel. A catheter is then threaded on the guide wire into the blood vessel.

Without question, this demonstrates that Liu's needle is not a catheter.

In addition, while the Examiner conceded that "Liu [] and Davidson in combination is silent to a cap coupled to the guidewire/intervention device," (Office Action mailed January 9, 2007, p. 2.), the Examiner concluded (Id., p. 3):

It would have been obvious to one of ordinary skill in the art to modify the device of Liu [] in view of Davidson with a cap as taught by Fischell [] in order to provide a handle or sealing end to prevent contamination or leaking of fluids at the proximal end.

However, without conceding that such an interpretation of Liu is appropriate, to the extent that Liu's second entry 4 can be interpreted as being a side arm, Liu discloses that his second entry (Liu col. 3, lines 15-17):

has a one-way valve (5), such as a flap valve, which prevents backup of fluids such as blood through said second entry.

Liu further discloses that his second entry (Id. col. 2, lines 53-59):

... is divided by a valve (5) so that fluid (blood) flowing through the needle and common passage can not escape through the distal entry of the arm. Though the valve prevents flow of blood back through distal end of the arm, it will allow a guide wire to enter into the lumen of the needle already in place in the blood vessel.

In addition, Liu discloses (Id. col. 4, lines 7-9.):

Using the device as taught, it is possible to minimize exposure to both the patient and the care-giver to infections.

Thus, after reading Liu, one skilled in the art would not have been motivated to modify Liu's device by adding a cap to his second entry "to prevent contamination or leaking of fluids at the proximal end."

Thus, none of Liu, Davidson and Fischell, alone or in combination, discloses or suggests the subject matter covered by claims 1-26. There is no suggestion to combine these references to provide this subject matter, and, even if the references were combined, the result would not be the subject matter covered by claims 1-26. Applicant therefore requests reconsideration and withdrawal of the rejections of claims 1-26 under 35 U.S.C. § 103(a) as being unpatentable over Liu in view of Davidson and further in view of Fischell.

The Examiner also rejected claims 1-26 under 35 U.S.C. § 103(a) as being unpatentable over Liu in view of Davidson, and further in view of U.S. Patent No. 5,357,961 ("Fields"). However, as noted above, contrary to the Examiner's characterization, Liu does not disclose the catheter/side-arm tube combination required by claims 1-26. None of Liu, Davidson and Fields, alone or in combination, discloses or suggests the subject matter covered by claims 1-26. There is no suggestion to combine these references to provide this subject matter, and, even if the references were combined, the result would not be the subject matter covered by claims 1-26.

Applicant therefore requests reconsideration and withdrawal of the rejection of claims 1-26 under 35 U.S.C. § 103(a) as being unpatentable over Liu in view of Davidson and further in view of Fields.

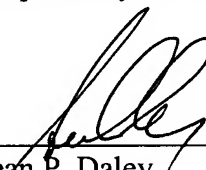
Conclusion

For these reasons, and the reasons stated in the Appeal Brief, Applicant submits that the rejection of claims 1-26 should be reversed.

Payment for the Notice of Appeal is enclosed. No additional fees are believed to be due in connection with the filing of this request for review. However, to the extent fees are due, or if a refund is forthcoming, please adjust deposit account 06 1050, referencing attorney docket no. 01194-513001.

Respectfully submitted,

Date: March 2, 2007



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